

REMARKS

In the Office Action mailed on August 14, 2007, the Examiner withdrew the enablement rejection but maintained the obviousness rejection against claim 3 and claims 5-16 over Cook et al. (US 6,395,782) in view of Horrobin et al. (US 6,245,811).

No claim amendment has been introduced and the Office Action cited no new art. The subject matter of the claims at issue has already been considered by the Examiner *vis a vis* the same references in the obviousness context. Therefore, the remarks presented here are believed to be appropriate for consideration in after final practice. Reconsideration of the merits of this application is respectfully requested.

In maintaining the obviousness rejection and in responding to the applicant's argument, the Examiner asserts that the applicant agrees that Cook et al. indicate treatment of subjects with conditions that include rheumatoid arthritis and treatment of a condition would reduce the symptoms of the condition (page 5, lines 17-20 of the Office Action). Applicant herein reiterates that what Cook et al. taught was the use of conjugated linoleic acid (CLA) for extending the survival time or reducing body weight wasting in subjects who have rheumatoid arthritis but not for reducing joint inflammation, redness, and swelling in these subjects. The only experimental evidence on the record shows that even though CLA can extend the survival time and reduce body waste wasting in a subject having a disease associated with the existence of autoimmune complexes as taught by Cook et al., it does not reduce the symptoms of the disease. Cook et al. taught with experimental support that CLA can extend the survival time and reduce body waste wasting in a subject having systemic lupus erythematosus. However, Yang et al. provided by the applicant in connection with the last response show that CLA treatment promoted the early onset of a symptom of systemic lupus erythematosus studied therein--proteinuria. See Fig. 4 of Yang et al., Immunopharmacology and Immunotoxicology, 2000, 22:433-449.

In addition, as explained in the last response in detail, rheumatoid arthritis is caused by antibody/antigen immune complex deposition and the evidence on the record suggests that CLA may aggravate rather than reduce antibody-initiated type III hypersensitivities such as rheumatoid arthritis by increasing antibody production. See Sugano et al. (Lipids, 1998, 33:521-527) and Yamasaki et al. (J. Nutr, 2003, 133:784-788) showing that CLA increases immunoglobulin (antibody) production. This is confirmed by Yang et al. which showed that

CLA treatment promoted the earlier appearance of antinuclear antibodies as well as proteinuria (Figs. 3 and 4 of Yang et al.).

Given that the evidence on the record (Yang et al., Sugano et al., and Yamasaki et al.) all show that CLA is unlikely to reduce symptoms of a disease associated with the existence of autoimmune complexes such as rheumatoid arthritis and the Examiner has not provided any evidence to the contrary, it is respectfully submitted that the present invention is not obvious.

With respect to the Examiner's assertion that "[r]eduction of symptoms is intrinsic to the method of treatment" (page 6, lines 12-15 of the Office Action), it is respectfully noted that what is inherent in the prior art, if not known at the time of the invention, cannot form a proper basis for rejecting the claimed invention as obvious under § 103. *See In re Shetty*, 566 F.2d 81, 86 (CCPA 1977).

With respect to Horrobin et al., the Examiner appears to agree with the applicant that CLA ester was not known at the time the Horrobin application was filed or issued to specifically be effective against rheumatoid arthritis (page 6, lines 1-6 of the Office Action). However, the Examiner asserts that Cook et al. specifically teach treatment of rheumatoid arthritis with CLA, and because Horrobin et al. teach the use of esters of CLA, the use of the esters for arthritis treatment would be obvious (page 6, lines 5-8 of the Office Action). As discussed above, Cook et al. do not make it obvious that CLA can reduce the symptom of joint redness and swelling of rheumatoid arthritis as recited in the claims at issue. Therefore, the combination of Cook et al. and Horrobin et al. does not make it obvious that an ester of CLA can reduce the symptom of joint redness and swelling of rheumatoid arthritis as recited in the claims at issue.

Applicant notes that under the new U.S. Supreme Court decision of *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. ___, 82 USPQ 2d 1385 (U.S. 2007), it remains necessary to identify a reason why one of ordinary skill in the art would have combined the prior art elements in a manner as claimed. *See Examination Guidelines for Determining Obviousness*, 72 Fed. Reg. 57526, 57534 (October 10, 2007).

It is acknowledged that a reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings (page 5, line 1 of the Office Action). However, as discussed in detail above, Cook et al. do not teach and one of ordinary skill in the art would not reasonable infer that CLA can

reduce joint redness and swelling in arthritis patients given the evidence to the contrary. Similarly, Horrobin et al. do not teach and one of ordinary skill in the art would not reasonably infer from Horrobin et al. that an ester of CLA can be used to treat rheumatoid arthritis. Therefore, in contrast to the reason provided at lines 16-18 on page 4 of the Office Action, it is not the case that Cook et al. and Horrobin et al. teach two compositions each of which is useful for the same purpose. Accordingly, the pending claims are not *prima facie* obvious as alleged in the Office Action.

In summary, given the unpredictable nature of the biotechnological art and the only experimental evidence (Figs. 3 and 4 of Yang et al.) on the record shows the opposite of the subject matter in the claims at issue, the claims at issue are not obvious.

No extension of time is believed to be necessary and no fee is believed to be due in connection with this response. However, if any extension of time is required in this or any subsequent response, please consider this to be a petition for the appropriate extension and a request to charge the petition fee to Deposit Account No. 17-0055. No other fee is believed to be due in connection with this response. However, if any fee is due in this or any subsequent response, please charge the fee to the same Deposit Account No. 17-0055.

Respectfully submitted,



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